

AMENDED CLAIMS-MARKED UP VERSION

2. (amended) The method according to claim 1, wherein the fat-containing food contains ~~from at least~~ about 10 kcal% fat.

REMARKS

Claims 1-12, 19-24 and 26-27 are pending in the above-referenced application. Claim 2 has been amended to more distinctly claim that which Applicants regard as their invention.

1. The Rejections Under 35 U.S.C. §112, Second Paragraph

Claim 2 has been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. In response, claim 2 has been amended to recite "at least about 10 kcal% fat". Therefore, the rejection has been overcome and the rejection should be withdrawn.

2. The Rejection Under 35 U.S.C. §103

Claims 1-12, 19-24, and 26-27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US 5889002, WO9726265 and WO9903861). Specifically, the Office Action states:

Applicant asserts that the compounds disclosed by Nielsen et al. is very different from the compounds of the general formula I herein, but fails to point out specifically what is the difference. Applicant's assertion regarding the difference in compounds of the general formula I is not found persuasive since the compounds of Nielsen et al. (citations omitted) are clearly seen to be same as the instant compounds of the general formula I, covering the instant elected species. Applicant further asserts that the instant application also discloses that intracerebroventricular[sic] administration of the potassium channel openers minoxidil and pinacidil increase intake of food by mice (see page 4 of Applicant's response). However, the instant claims are not limited to the intracerebroventricular administration of the potassium channel openers minoxidil and pinacidil in mice.

As discussed in the previous Office Action, the active compounds herein are not only known to be potassium channel openers, but also known to be useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease, diabetes and obesity and decreasing weight gain according to Nielsen et al. Moreover, since the amount of fat-containing food to be consumed or fat intake is well known to be tightly associated with risk of obesity, hypertension, diabetes, and coronary heart disease according to the prior art, one of ordinary skill in the art would have reasonably expected that the active compounds of Nielsen would have beneficially therapeutical effect on reducing the consumption of fat-containing food, absent evidence to the contrary.

Furthermore, Nielsen's method inherently reduces the consumption of fat-containing food, as claimed herein since Nielsen's method steps are same as the instant method steps and that the range of effective amounts of active compounds therein to be administered is within the instant range. (citation omitted) Thus, the instant claimed method is inherently present in the prior art.

Additionally, it is noted that Applicant admits herein that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake since Applicant employs an obese Zucker rat as the testing model for the instant claimed method. See page 23 lines 1-15 in the specification. Thus, Applicant clearly acknowledges that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake as discussed by the examiner above. Therefore, Applicant's own admission supports the examiner's position for the motivation for the instant invention.

Applicant's testing results in the specification at page 23 lines 1-15 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive since the results on the employment of the particular compound on obese rats show expected therapeutic effects as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected

based on the cited prior art. Expected beneficial results are evidence of obviousness (citation omitted). Further, testing herein merely demonstrate a single particular compound within the broad genus of the instant claims. Thus the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the activities[sic] in the claimed method herein. (citation omitted).

Applicants respectfully traverse the rejection. First, Applicants wish to respond to the assertion made in the Office Action at the bottom of page 3 that "Applicant's assertion regarding the difference in compounds of the general formula I is not found persuasive since the compounds of Nielsen et al. are clearly seen to be the same as the instant compounds of the general formula I, covering the instant elected species." Applicants wish to clarify that in the response to the Office Action dated January 15, 2002, Applicants were trying to distinguish the potassium channel opener, diazoxide, not encompassed by the instant claims, from the potassium channel openers encompassed by Formula I. Again, Applicants respectfully point out that results are only provided for diazoxide.

Second, in response to the assertion that Nielsen's method inherently reduces the consumption of fat-containing food, Applicants respectfully point out that the rejection is under 35 U.S.C. §103. The doctrine of inherency is only applicable with respect to anticipation rejections not obviousness rejections. A retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination. In re Newell, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989), cert. denied, 493 U.S. 814 (1989). Furthermore, in determining obviousness, "[i]t is not pertinent whether the prior art device possesses the functional characteristics of the claimed invention if the reference does not describe or suggest its structure. By way of contrast, in determining novelty, a showing that the "prior art reference cited as anticipating a claimed invention...lack[ed]the characteristics of the claimed invention would in fact negate the assertion that the claimed invention was described in the prior art." In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed.Cir. 1990).

Applicants further point out that the method of the present invention can be distinguished from the method disclosed in the cited references. There is absolutely no suggestion in the cited Nielsen references that the compounds of Formula I could be used to reduce the consumption of fat-containing food. In contrast, on page 22, lines 5-14 of the instant application, it is stated that the amount administered should be effective to provide a clinically significant effect against consumption of fat food and it is suggested in the specification that the compositions conveniently be administered at mealtimes. It is not clear that administering the compound of formula I using the procedures taught in the cited Nielsen references would necessarily result in reducing consumption of fat-containing food. Nothing is said regarding time of administration and the dosage ranges are not the same. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Rapoport v. Dement*, 59 USPQ2d 1215 (Fed. Cir. 2001).

Finally, Applicants respectfully point out that the reduction of consumption of fat-containing food was totally unexpected. In the Nielsen references, the compounds of formula I were suggested to treat various disorders. It was suggested in the Nielsen references that the compounds could prevent diabetes and reduce obesity as a consequence of reducing hyperinsulinemia. There was no suggestion that the compounds of formula I could actually reduce consumption of fat-containing food. The results in the Example in the instant invention indicate that when the animals given a choice of three different types of meals: 45%fat, 10%fat and 4%fat, they normally prefer the meals with the highest amount of fat. However when animals have been given a compound of the present invention (especially the compounds mentioned in the test) then they are not interested in the fat meals (10%fat and 45%fat) but prefer the altromin feed (4% fat). They exhibit a significantly higher preference for the lower fat diet than even animals given diazoxide. These results are indeed unexpected.

In view of the above arguments and amendments, Applicants assert that the rejections have been overcome. Therefore, Applicants respectfully request the rejections be withdrawn.

4. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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